

K111666

EMERGO GROUP

SEP - 7 2011

## Section 005 - Traditional 510(k) Summary

As required in 21 CFR807.92, we hereby submit this 510(k) Summary.

### 510(k) owners name, address, phone, fax, contact person & preparation date

The 510(k) owner is NeoDental Chemical Products Co., Ltd.

3-1-3 Hiroo, Shibuyaku, Tokyo, Japan 150.

Phone - 3 (3400) 3768,

Fax - 3 (3499) 0613.

The contact person is Mr. Nobuki Ishikawa, Treasurer, NeoDental International, Inc.

510(k) preparation date - 28 May 2011

### SUBJECT DEVICE:

#### Name of the device, trade name, proprietary name, and classification name

Trade name: Evadyne Temporary Crown and Bridge Resin

Common name: Temporary Crown and Bridge Resin

Classification name: Crown and Bridge, Temporary, Resin (21 CFR 872.3770, Product Code EBG).

### Device Description:

NeoDental Chemical Products, Inc, (NeoDental) wishes to submit their **Evadyne® Temporary Crown and Bridge Resin** for 510(k) clearance.

Evadyne®, (shown in **Figure 1**) is a yellowish translucent, lower viscosity, light-cured temporary restoration material for direct filling. After curing, Evadyne® can be removed in one piece when the permanent restoration is to be placed.

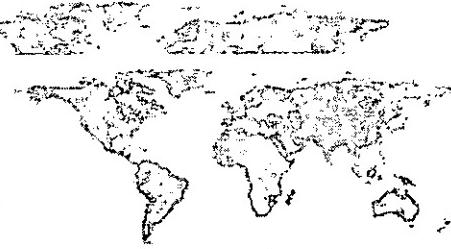


Figure 1

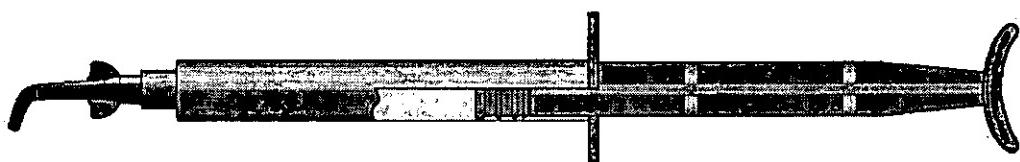
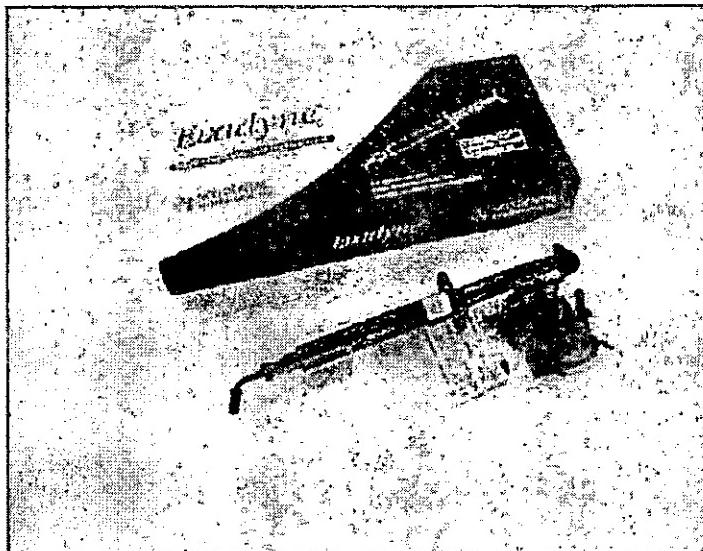
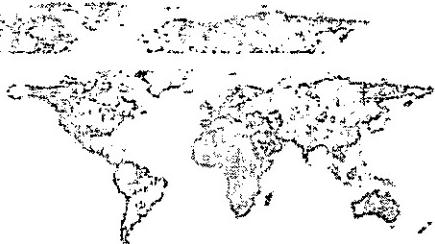


Figure 2 - Syringe

Evadyne® is packaged as a multiple use syringe, with new tips being attached for each patient. The syringe can be used until empty. The syringe is kept capped between uses and is fitted with a new tip just prior to use. The syringe is cleaned with an alcohol wipe before and after use.

#### Indication for Use:

Evadyne® is a light cured single-component material for the temporary restoration of crowns, bridges, or similar dental prostheses. Evadyne is intended for the general dental patient population.

**Intended Use:**

Evadyne® is a light cured, single-component material for temporary restoration. Evadyne® is easily expressed through the plunger type syringe and the low viscosity paste allows for direct filling. The product is delivered directly into the prepared cavity using single-use, disposable tips. Evadyne® is a tasteless, odorless restoration, provides good sealing and can be easily removed when the permanent restoration is to be placed.

The Indications for Use and Intended Use information for the predicate product are equivalent and are reproduced below:

**PREDICATE DEVICE:**

The legally marketed predicate for the Evadyne® Temporary Crown and Bridge Resin is Fermit-N, (K934978), a light-curing temporary filling material produced by IvoClar N.A., Inc.

**Indications for Use:** Temporary restoration material

**Intended Use:** - Temporary restorations in the inlay/onlay technique for temporary restorations of all kinds. Relining material for prefabricated temporary crowns and bridges made of polycarbonate or methacrylates.

As is documented in the comparison of Indications For Use and Intended Use, the Evadyne® temporary bridge and crown resin and the Fermit N temporary bridge and crown resin are indicated for the same use, share the same clinical indication, clinical setting, target population, anatomical sites, intended use, prescription requirement, storage conditions and method of application.

**Technological characteristics – Evadyne® versus the predicate device**

A technical comparison of the subject device to the predicate device is detailed in the *Substantial Equivalence* discussion below (see the comparison table below).

Both Evadyne® and Fermit N are indicated for the same use. Evadyne was designed, tested and compared to Fermit N.



Similarities: Evadyne is substantially equivalent to the predicate device in:

- Device description,
- Intended use,
- Indication for use,
- Requirement for prescription use,
- Storage conditions,
- Mechanism of polymerization (light polymerized)
- Container/closure

Differences: There are slight differences between the Fermit N product and Evadyne.

- Composition – Evadyne uses a fluoroaluminosilicate glass as a filler. Fermit uses a co-polymer. Both of these compounds are used to maintain the properties of the filling material.
- Flow, flexural strength, and syringe type differ due to Evadyne is formulated to have a lower viscosity for better ease of use (application directly to the prepared cavity from the syringe). The lower viscosity also results in Evadyne having a lower flexural strength relative to Fermit N.

We conclude that for all significant parameters, Evadyne is substantially equivalent to Fermit N. These include the photocatalytic material and mechanism, intended use, indication for use, most physical properties, design, packaging and performance.

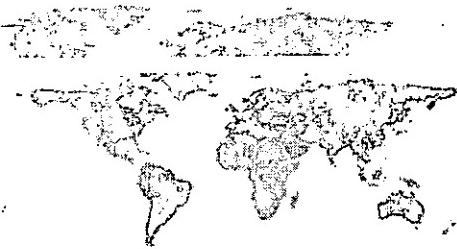
#### Non clinical test data:

The Evadyne® temporary crown and bridge resin has been evaluated according to recognized consensus standards defined in ISO 10993-1. Results were found to conform to requirements (see section 15). Test data is further discussed in Section 15.

21 CFR 872.3770 lists the following recognized consensus standards:

- ANSI/ADA Specification No. 53 – Polymer-Based crowns and Bridge Resins: 1999/2005,
- ANSI/ADA Specification No. 80 – Dental Materials – Determination of Color Stability 2001/2007,
- ISO 10477:2004 – Dentistry – Polymer-based crown and bridge materials
- ISO 7405:2008 - Evaluation of biocompatibility of medical devices used in dentistry.

However, NeoDental believes that these tests are not relevant for the following reasons:



- Evadyne is a TEMPORARY FILLING material for cavities. Physical properties have evaluated according to ISO 4049, but the other tests required in ISO-4049 are not applicable to Evadyne for the following reasons:
  - ISO-10477 is for crown bridge cement. The tests relating to Evadyne are same as ISO 4049.
  - ANSI Spec 53 is identical to ISO-10477
  - ANSI Spec 80 is for color stability of products which are to be applied to permanent restorations having color shadings.

### Biocompatibility of Evadyne

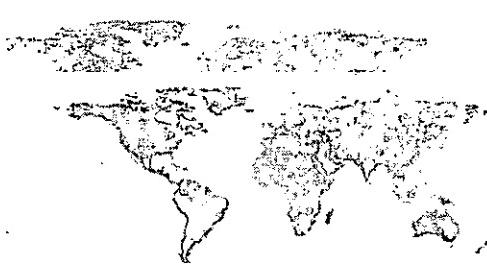
According to ISO 10993-1 Annex A, Evadyne can be categorized as shown Table 1.

Table 1

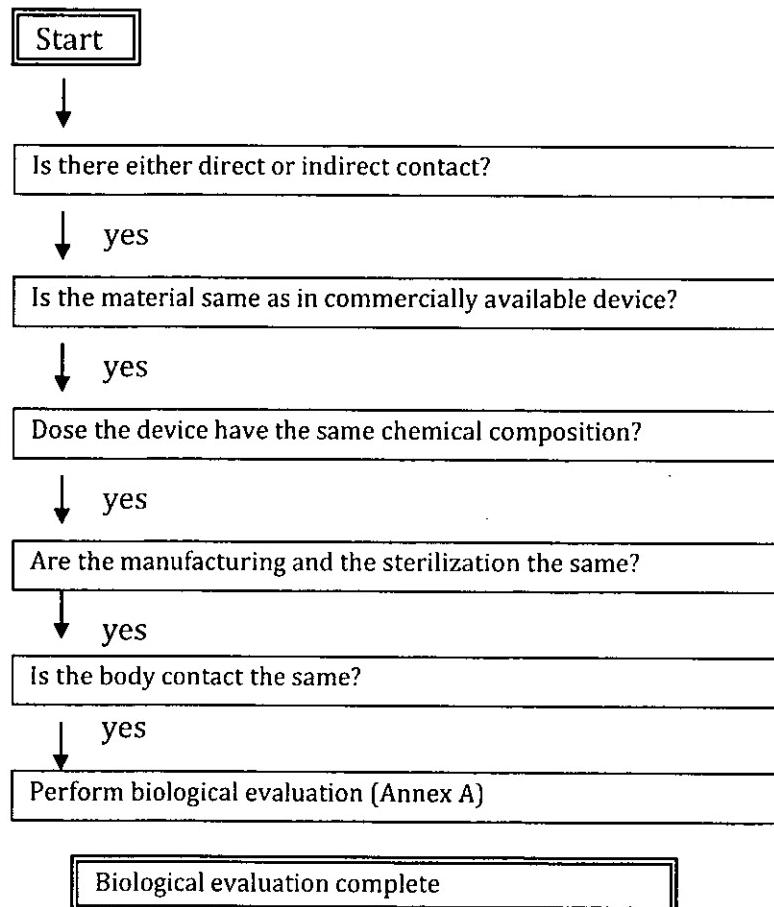
Medical device categorization by			Biological effect for consideration
Nature of body contact	Category	External communicating device	- Cytotoxicity - Sensitization - Irritation - Systemic toxicity - Subchronic toxicity - Genotoxicity - Implantation
	Contact	Tissue/bone/dentin	
Contact duration		B (>24 h to 30 days)	

### < Biological evaluation >

Urethane resin (UDMA), main ingredient of Evadyne, has been widely used in dental restorative materials as a "composite resin". Additionally, fluoroaluminosilicate glass, an ingredient of Evadyne, has been widely used in composite filling materials.



According to ISO 10993-1, the systematic approach to a biological evaluation for Evadyne is as follows.



**Table 2**

Biological test	Date/ Test house	Method
Cytotoxicity	2002.9.18/ Covance Lab.	Agar Overlay Assay
Sensitization	2002.9.12/ Covance Lab.	Maximization method / Guinea Pig
Genotoxicity	2002.9.16/ Covance Lab.	Bacterial strain: (TA98, TA100, TA1535, TA1537, WP2uvrA) S9+ & S9- method
Irritation	2001.9.27/ In vitro international	Irritation Assay System (Ocular irritation test method)

NeoDental did not conduct the biological tests for systemic toxicity, subchronic toxicity and implantation. Testing conducted and the long-use of this product has demonstrated safety for its intended use. Total Evadyne sales equal 76,000 sets from 2005 until now. No incidents or adverse events have been reported since 2005. Furthermore, Evadyne holds the CE mark which was renewed in October 2010.

### Summary

NeoDental concludes that Evadyne is substantially equivalent to the predicate device in characteristics and technology.

End of 510(k) Summary Section



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Neodental Chemical Products Company, Limited  
C/O Mr. Robert Seiple, MPM, RAC  
Senior Consultant  
Emergo Global Consulting, LLC  
611 West 5<sup>th</sup> Street  
Austin, Texas 78701

SEP - 7 2011

Re: K111666

Trade/Device Name: Evadyne® Temporary Crown and Bridge Resin  
Regulation Number: 21 CFR 872.3770  
Regulation Name: Temporary Crown and Bridge Resin  
Regulatory Class: II  
Product Code: EBG  
Dated: June 13, 2011  
Received: June 14, 2011

Dear Mr. Seiple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson".

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section 004 - Indication for Use****INDICATIONS FOR USE STATEMENT**510(k) Number (if known): K111666Device Name: Evadyne® Temporary Crown and Bridge Resin

## Indications for Use:

Evadyne® is a light cured single-component material for the temporary restoration of crowns, bridges, or similar dental prostheses. Evadyne is intended for the general dental patient population.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental DevicesPage 1 of 1510(k) Number: K111666